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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/147,801 | 03/11/1999 | BO NIKLASSON | REF/29713/NI | 2230 |

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[REDACTED] EXAMINER

WORTMAN, DONNA C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1648 | 32 |

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/147,801 | NIKLASSON, BO | |
| | Examiner Donna C. Wortman, Ph.D. | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 January 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5,7,9,11 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 5 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4,7,9,11 and 15-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) Interview Summary (PTO-413) Paper No(s) _____ .
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____ .

Claim 19 was canceled in Paper No. 30. Claims 1-3 and 5 remain pending but withdrawn from examination as drawn to a non-elected invention. Claims 4, 7, 9, 11, and 15-18 are under examination.

Based on Applicant's remarks in Paper No. 30, claims 7, 11, 15, and 16 are interpreted as reciting an "antibody-binding part" of a protein that is the specific structural part of a protein that is recognized by an antibody such that the antibody can bind to that structural part of the protein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 11, 16, 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 11, and 16 are indefinite in reciting "homologous sequences having at least 75% homology to SEQ ID NO: ..." for reasons of record in rejecting claims in the Office action mailed December 15, 2000, as Paper No. 14. In particular, the specification does not define either "homologous sequences" or "homology" in such a way that one of skill in the art could reasonably determine what Applicant intends by the cited terminology.

Applicant has argued that, in the case of claim 16, "homology" was determined by comparing the nucleotide sequences of virus isolates by alignment as shown in Table 2; that in the case of claim 4, amino acids corresponding to an ORF of 188 amino

acids were compared to known amino acid sequences for cardioviruses in terms of both identity and similarity; and that one of skill in the art knows to adjust sequence search parameters in order to obtain the type of search result desired.

This argument has been considered but not found persuasive as the metes and bounds of what Applicant intends to claim remain unclear. Based on Applicant's remarks, it appears that "homology" means "identity" when applied to polynucleotide sequences, while "homology" can mean either "identity" or "similarity" or both when applied to amino acid sequences, and that "75% homology" can be obtained in any number of ways, depending on how one chooses to set the search parameters.

Claim 17 is confusing as it depends from claim 4 and recites "comprising an antigen" since it is not clear whether the "antigen" is the same as the "antigenic fragment" of claim 4 or some additional, undefined, component.

Applicant has stated that "antigen" is different from "antigenic fragment" and pointed to the specification at page 4, line 30, to page 5, line 14, as providing a method for determining if a protein or fragment thereof is an antigen.

These remarks have been considered but not found persuasive; page 4, line 30, to page 5, line 14, describe an immunofluorescence test to determine antibody titers in animals inoculated with cell culture supernatants from virally infected cells and do not mention a protein or fragment thereof that is an antigen.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which

Art Unit: 1648

it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 7, 9, 11, and 15-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protein SEQ ID NO:4 does not enable a protein having at least 75% homology to SEQ ID NO:4, or an antigenic or antibody-binding portion of SEQ ID NO:4, nor an antigenic or antibody-binding portion of a protein having at least 75% homology to SEQ ID NO:4, nor a viral subunit. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record.

Applicant has argued that the methods disclosed would enable one of skill in the art to make proteins with the required degree of homology and to determine whether or not they are antigenic or bind antibodies.

This argument has been considered but not found persuasive. The claims encompass any protein that is at least 75% homologous to SEQ ID NO:4, and any antigenic fragment or antibody-binding portion of such protein, without limitation as to antigenic or antibody-binding specificity; it would require undue experimentation for one of skill in the art to practice the invention as claimed since it encompasses proteins and fragments that are antigenic in any setting and that bind to any antibody.

Claims 15, 18, 9, 11, 16 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record.

Art Unit: 1648

Applicant has argued that the specification discloses the isolation of three different virus isolates that exhibit CPE and react with a panel of human sera in an IFT; that the virus isolates exhibit sizes and structures compatible with picornavirus based on electron microscopy; that the three virus isolates kill suckling mice when inoculated intracerebrally; and that the fact that human sera collected from patients with various diseases reacted with one or more of the three viruses represents statistical evidence that supports the involvement of the instant viral isolates in pathological diseases.

These arguments have been considered but not found persuasive. The evidence cited by Applicant shows that the three virus isolates are lethal to suckling mice when inoculated intracerebrally, and that certain human sera contain antibodies that immunoreact, or cross-react, with cells infected with the viruses. While there may be statistical correlation, correlation is not equivalent to causation of any human disease. Further, even if it were to be discovered that the isolated viruses cause some human disease, the specification as filed does not teach how to use the parts of the virus disclosed as a vaccine to prevent or treat any disease.

A claim limited to a protein comprising SEQ ID NO:4 would be allowable as previously indicated.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

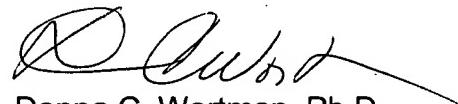
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
April 9, 2003